SUBJECT:	Fermilab Corrective & Preventive Action Procedure	**NUMBER:**	**1004.1001**
RESPONSIBILITY:	Quality Assurance Manager	**REVISION:**	001
APPROVED BY:	Head, Office of Quality and Best Practices	**EFFECTIVE:**	**03/31/10**

1.0 Purpose

The purpose of this procedure is to implement a corrective and preventive action (CAPA) program for continuous improvement in compliance with DOE O 414.1C Contractor Requirements Document Section 3c Management/Criterion 3 – Quality Improvement.

2.0 Scope

This procedure is followed when corrective and preventive actions are necessary to correct quality program nonconformities or opportunities for improvement.

3.0 Applicability

This procedure applies to Fermilab Research Alliance, LLC (including all legal entities under its exclusive control) and all its employees, contractors, subcontractors, and Fermilab users.

4.0 Responsibilities

4.1 The Fermilab Director

- Holds senior staff accountable for implementation of, and compliance with, this procedure

4.2 Division/Section/Center Heads

- Comply with and support this procedure for their areas of responsibility
- Ensure timely response, submittal, and implementation of Corrective & Preventive Action Plans (CAPs) that are appropriate to the level of risk associated with a nonconformity or opportunity for improvement
- Provide the necessary resources to develop and implement CAPs
- Analyze individual and collective nonconformities or opportunities for improvement to detect trends or potential systemic weaknesses

4.3 The Office of Quality and Best Practices (OQBP)

- Manages, improves and administers the Fermilab Corrective and Preventive Action Program
- Requests, reviews and tracks CAPs for nonconformities or opportunities for improvement relevant to the Fermilab Issues Management System
- Requests, reviews and tracks CAPs for nonconformities or opportunities for improvement identified during assessments or audits sponsored or conducted by OQBP
- Advises the Chief Operating Officer if a nonconformity appears to be reportable
- May analyze individual and collective nonconformities or opportunities for improvement to detect trends or potential systemic weaknesses

4.4 All Employees, Contractors, and Users

- Identify and report nonconformities and opportunities for improvement to line management
- Participate in corrective and preventive actions as requested by line management
- Complete corrective and preventive actions commensurate with the level of risk as assigned

5.0 Procedure

5.1 Corrective & Preventive Action Procedure

Figure 1 is an illustration of the generalized process for feedback and continuous improvement utilized in the Fermilab corrective and preventive action program.

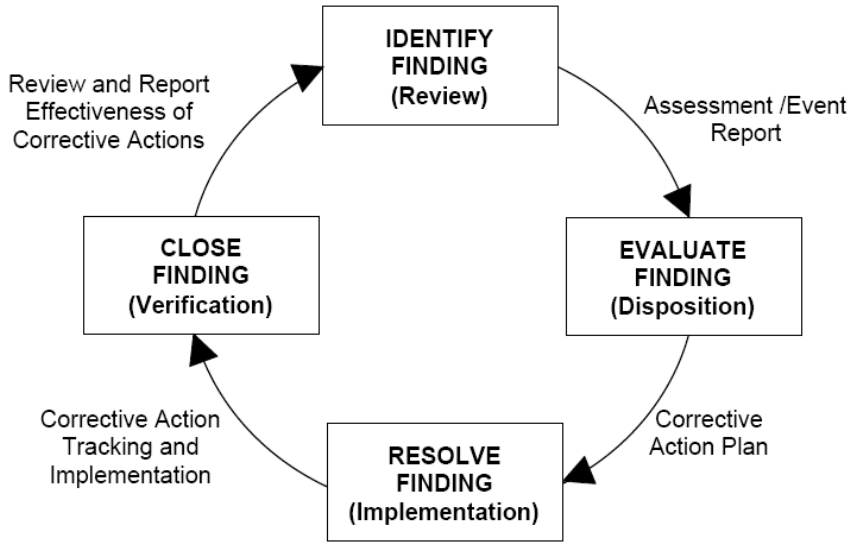

Figure 1. Feedback and Improvement

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5.1.1 The sequence begins with the identification and reporting of a nonconformity or opportunity for improvement.

All employees, contractors, subcontractors, and Fermilab users are encouraged to report any nonconformities or opportunities for improvement to their immediate supervisor. Other sources of nonconformities may be identified during routine item inspections and tests, reviews, assessments or audits. Persons leading such reviews, assessments or audits may request CAPs from affected line management in order to close open findings. In some cases OQBP may request CAPs from line management on behalf of persons who lead a Fermilab review, assessment or audit. OQBP may also request CAPs as a result of an assessment conducted by or sponsored by OQBP or for items entered into the Issues Management System.

5.1.2 Responsible line management will respond to the CAP request. Depending on the complexity of the nonconformity or opportunity for improvement, the response may contain a planned date for a completed corrective action plan (CAP), or it may contain a completed CAP. If the CAP is not submitted with the response, the responsible manager submits the CAP to the requestor at a later date as indicated in the response. The Fermilab Corrective Action Plan Form 1 1004.1001 Form 1 is used to submit a CAP.

Each CAP will contain detailed information regarding department/division/section/center responsible, who is designated to manage resolution, facts supporting the identification of root cause, lessons learned (where relevant), and timelines for resolution commensurate with the complexity, and actual or potential significance/risk.

A graded approach is used perform root cause analysis. This approach matches the risk level and severity of the nonconformity with the level of resources and depth of examination used to perform the root cause analysis. See the [Fermilab Root Cause Analysis Procedure 1004.1002] for guidance on conducting a root cause analysis.

During a root cause analysis the responsible person may question not only if existing controls need to be updated but also whether or not the activity has the correct controls under current operating conditions. Under these circumstances the Fermilab Graded Approach Procedure, 1002.1000 may be applied where the responsible person determines that corrective or preventive actions require a more formal approach to risk evaluation and control selection.

The CAP should also contain a description of opportunities for preventive actions that will be undertaken to prevent the occurrence of this or similar events in the same and / or different areas when such opportunities are identified. If corrective actions will require significant time to complete and implement, the CAP must include interim corrective and/or remedial (compensatory) measures that will be implemented pending completion of the corrective action to reduce the possibility of the event or condition recurrence. Where corrective actions require training or re-training, records of such training are maintained.

5.1.3 The requestor of the CAP reviews the response and CAP for:

- Completeness, and correct identification of the cause
- likelihood of resolving the identified root cause of the issue,
- likelihood of preventing recurrence in the area where identified,
- identification of lessons learned if applicable,
- likelihood of preventing the occurrence of similar issues in the same area or other areas of the laboratory.

5.1.4 Upon acceptance of the CAP, the responsible person implements the necessary actions

5.1.5 The responsible person notifies the requestor upon completion of the necessary actions

5.1.6 The requestor ensures completion is verified before closing the corrective action request.

5.1.7 After a corrective action request is closed, it may be subject to validation by the requestor, and/or responsible person, to determine the effectiveness of actions taken. Corrective actions are effective when the causal chain of events leading up to the problem or opportunity are broken and remain broken. Degree of validation will be commensurate with complexity, risk and cycle time associated with affected processes. Some corrective / preventive actions may be validated formally by inspections, tests, reviews, surveillances, audits or other assessments. Other issues may simply be monitored to ensure the ongoing effectiveness of the actions taken.

5.2 **Management Review of Corrective & Preventive Action Data**

Responsible line management will analyze individual and collective problems or opportunities for improvement to detect trends or potential systemic weaknesses, and to identify additional opportunities for preventive actions.

6.0 Records

Corrective & Preventive Action Plans
Reports of QA Reviews, Assessments, Audits, Inspections, Tests, etc

7.0 Review Cycle

7.1 Document Owner
URS QA Manager

7.2 Reviewers
OQBP Head
URS QA Manager
Div/sec/center QARs

7.3 Approver
OQBP Head

8.0 Policy and Program Documents

Directors Policy #10, Quality Assurance
1001 Integrated Quality Assurance (IQA)
1002.1000 Fermilab Graded Approach Procedure
[1004.1000 Fermilab Process Improvement Program]
1004.1001 Form 1 Fermilab Corrective & Preventive Action Plan Form 1
1004.1001 Guide 1 Fermilab Corrective & Preventive Action Plan Guide 1 to Form 1
[1004.1002 Fermilab Root Cause Procedure]

9.0 Definitions

Assessment: A review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.

Corrective Action: an action taken to eliminate the cause(s) of existing nonconformities (problems/opportunities) or other undesirable situation in order to prevent *recurrence*. It is a reactive, long-term solution to prevent the same problem from happening again by removing its source.

Nonconformity: a failure to meet a specified requirement.

Preventive Action: an action taken to eliminate the cause(s) of potential nonconformities (problems) in order to prevent occurrence. It is a proactive action before an unintended negative outcome takes place.
Remedial Action: an action taken to alleviate the symptoms of existing nonconformities or any other undesirable situation. Also known as correction or compensatory action, remedial action is used to minimize the effects before the root cause and best solution may be identified. It is a reactive, short term action to stop immediate effects of the problem.

Root Cause: The fundamental cause of a nonconformity or event which, when eliminated should prevent recurrence of the nonconformity or event.

10.0 References

DOE O 414.1C Quality Assurance – Contractor Requirements Document, Attachment 2 Management/Criterion 3 – Quality Improvement

DOE G 414.1-5 Corrective Action Program Guide

Table of Revisions

Author	Description	Revision	Date
Jed Heyes	Draft- Separated from OQBP IMS Issues Tracking Procedure Added reference to a Guide in addition to a Form.	000	08/06/08
Jed Heyes	Changed formal root cause to complex root cause and informal investigation to simple root cause. Added definitions for the terms.	000 A1	08/08/08
Jed Heyes	Clarified complex and simple corrective / preventive actions. Introduced a new Form 1 for simple actions (used in low risk situations) and reassigned original Form 1 to Form 2 for complex actions.	000 A2	10/26/08
Jed Heyes	Updated from document review with Bob Grant, & Nathan Weed	000 A3	12/23/08
Jed Heyes	All changes accepted upon OQBP approval on 01/13/09. Promotion to C life cycle for simultaneous review (B life cycle) and use (C-validation life cycle) by QARs & QAEs during As-Is assessments..	000 C	02/02/09
John Martzel, Jed Heyes	Updated the document to resolve CAP OQ-20100104-01 generated by 2009 DOE Assessment of Fermilab Quality Assurance Program. Key changes: • Removed references to simple and complex corrective actions and root causes and replaced with references to a graded approach • Defined the term nonconformity • Removed 1004.1001 guide 2, Complex Corrective and Preventive Action Plan, from the process • Removed Appendix describing required root cause depth (simple/complex)	001	03/25/10